

### **REMARKS**

Claims 63, 65-68, and 70-75 constitute the pending claims in the present application. Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the prior Office Action.

1. Applicants note with appreciation that the submission received October 20, 2005 has been entered in full.
2. Claims 63, 65-68, and 70-75 are rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Ingham et al. (US Patent No. 5,844,079) in view of Tabin et al. (US Patent No. 6,844,775). Applicants traverse this rejection and contend that the rejection is moot in light of the amended claims.

The MPEP outlines the basic tenets that must be applied when evaluating whether an invention is obvious in view of a combination of references. MPEP 2141. As articulated by the court, in making an obviousness determination, the claimed invention must be considered as a whole; the cited references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination; the references must be viewed without the benefit of impermissible hindsight afforded by the claimed invention; and reasonable expectation of success is the standard with which obviousness is determined. *Hodosh v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143 n.5, 229 USPQ 182, 187 n.5 (Fed. Cir. 1986). In rejecting the pending claims in view of Ingham et al. and Tabin et al., the Examiner has departed from these basic points. Accordingly, Applicants contend that the combination of Ingham et al. and Tabin et al. fail to undermine the patentability of the claimed invention.

As outlined in detail in Applicants' previous response, Ingham et al. actually teach away from using hydrogels as part of a topical preparation. Rather, the portions of Ingham et al. relied upon by the Examiner describe the use of hydrogels and other implants. The term implant refers to an object or device that is inserted or embedded **within** the body. (The American College Dictionary, Third Edition). The plain meaning of the term is inconsistent with and, in fact, teaches away from the topical preparations presently claimed.

In an apparent attempt to augment the disclosure of Ingham et al., the Examiner has combined Ingham et al. with Tabin et al. However, Ingham et al. does not merely lack an element of the presently claimed invention, Ingham et al. teaches away from the presently

claimed invention. As such, there would have been no motivation to combine the teachings of Ingham et al. with Tabin et al. As indicated above, the cited references themselves must suggest the desirability of making the combination. MPEP 2141. Such a suggestion is absent here. Accordingly, the combination of Ingham et al. and Tabin et al. does not constitute a proper basis for rendering the claimed invention obvious.

Furthermore, the desirability of combining the references is provided only from Applicants' disclosure. Neither Ingham et al. nor Tabin et al. teach or suggest the use of hedgehog polypeptides in, for example, the promotion of hair growth. The feasibility and desirability of this use is provided by the present application. As outlined above, consideration of the prior art using hindsight obtained after consideration of Applicants' disclosure is improper and cannot form the basis of a rejection under 35 U.S.C. 103.

In view of the foregoing arguments, Applicants contend that the cited references fail to render the claimed invention obvious. Nevertheless, to expedite prosecution, Applicants have amended the claims to more particularly point out the claimed subject matter. Specifically, Applicants have amended the claims to more particularly point out that the claimed preparation is formulated for topical application to scalp. Such preparations are especially useful for methods in which the preparation is part of a medicament for modulating hair growth. Ingham et al. and Tabin et al. fail to teach or suggest the desirability of making preparations for topical administration to the scalp, and thus Ingham et al. and Tabin et al. fail to undermine the patentability of the amended claims.

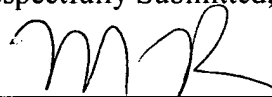
Applicants' amendments are not in acquiescence to the rejection. Applicants reserve the right to prosecute claims of similar or differing scope. In light of Applicants' arguments and amendments, reconsideration and withdrawal of this rejection is requested.

**CONCLUSION**

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Should an extension of time be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this submission be charged to **Deposit Account No. 18-1945, under Order No. CIBT-P03-031.**

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Respectfully Submitted,



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